

UNITED STATES PATENT AND TRADEMARK OFFICE

MERCE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

PPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,654	11/05/2001	Gotz Nowak	ALBRE17	5284
23599 75	590 10/26/2004		EXAM	INER
MILLEN, WE	HTE, ZELANO & BRAT	SAUCIER, SANDRA E		
2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			ART UNIT	PAPER NUMBER
			1651	
			DATE MAIL ED. 10/26/200	1

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)	
09/890,654	NOWAK ET AL.	
Examiner	Art Unit	
Sandra Saucier	1651	

Before the Filing of an Appeal Brief --The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 04 May 2000 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applican must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: a) The period for reply expires months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) a set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed may reduce any earned patent term adjustment. See 37 CFR 1.704(b). **NOTICE OF APPEAL** 2. The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on 27 August 2004. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). **AMENDMENTS** 3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below): (b) They raise the issue of new matter (see NOTE below): (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: . (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): _____. 6. 🔲 Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. X For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: 9,10,15 and 17. Claim(s) withdrawn from consideration: AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1). 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment. 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s): andra Saucier

Primary Examiner Art Unit: 1651

Application/Control Number: 09/890,654

Art Unit: 1651

ATTACHMENT

Applicants argue that a skilled worker would have recognized that the inventors had possession at time of filing of a kit comprising a standard curve. Applicants point to page 3, ls. 17-20, page 4, lines 5-8, page 9 lines 4-7, page 10, lines 10-15, and Figure 1.

Please note that there is no page 10 of the specification, page 10 is the first page of original claims, and no mention of a standard curve is found at lines 10–15. Also, no Figure 1 is part of the specification as filed. Applicants point to the priority document of PCT/DE00/00330 to show evidence of the presence of a Figure. However, the figure submitted in the response of 8/25/04, while part of the parent application PCT/DE00/00330, has not been translated from German to English as the rest of the specification has prior to filing in the US. This raises a question of whether the instant application is more correctly termed a CIP of PCT/DE00/00330, since it is assumed that if the applicants had wished the figure to be part of the national filing, they would have 1) had the figure translated into English as the rest of the specification was, and 2) submitted it with the translated national application. It appears that neither of these actions was taken.

This question aside, the citations on pages 3 and 4 recite a method of comparison of present data with "previously determined standard curves". The citation on page 9 recites that Fig. 1 shows "the obtained standard curve.". None of these recitations points to the inclusion of a standard curve with the kit. Although the use of standard curves is routine as stated by applicants, the generation of the standard curve is usually done in the laboratory where the unknown sample is tested. This is to insure that variations in volume, time, temperature, optics, samples and reagents are included in the standard curve. It is less likely that for this type of assay that a standard curve generated in another laboratory is used as reference, particularly because each putative inhibitor would generate a distinct standard curve as explained in the final office action.

Application/Control Number: 09/890,654

Art Unit: 1651

In summation, no evidence is present in the as-filed specification which would lead one to the claim kit including a standard curve.

Even, for the sake of argument, if the disputed subject matter was assumed not to be new matter, it is well settled that inclusion of printed matter does not change the inherent properties of a composition See *In re* Nagi, 70 USPQ2d 1862 (CAFC 2004).

Claims 9, 10, 12, 15 and 17 are rejected under 35 USC § 112, first paragraph.

Claims 9, 10 and 12 remain rejected under 35 USC § 102(b) as being clearly anticipated by Han *et al.*

Claims 9, 10, 12, 15 and 17 remain rejected under 35 USC § 103(a) as being unpatentable over US 5,547,850 in view of US 5,702,912 or Houbouyan et al.

SANDRA E. SAUCIER PRIMARY EXAMINER